

Exhibit B

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Failure of hepatitis B immune globulin to protect against exp infection in chimpanzees.

[Wahl M](#), [Iwarson S](#), [Snoy P](#), [Gerety RJ](#).

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To study experimentally the protective effect of post-exposure prophylaxis against hepatitis B (HB), a special preparation of hepatitis B immune globulin (HBIG) was injected intravenously (i.v.) into three chimpanzees simultaneously with, or at different time intervals after, intravenous injection of a titred inoculum of hepatitis B virus (HBV). The HBIG was given either simultaneously with the HBV inoculum, at 4 hours after, or at both 4 hours and 4 weeks after the HBV injection. A fourth chimpanzee received a standard preparation of HBIG intramuscularly (i.m.) at both 4 hours and 4 weeks after receiving the HBV injection. A fifth animal received HBIG i.v. 4 hours after the HBV inoculum and at the same time received its first of three HB vaccine injections. All chimpanzees were followed for 1 year.

The animals which received HBIG simultaneously with HBV or received HBIG plus vaccine had no serological or biochemical sign of HB during follow-up. The three animals which received HBIG after HBV inoculation all developed HBs-antigenemia and serum aminotransferase (ALT) elevations. HBsAg did however appear in serum several weeks later than expected for the HBV inoculum used. Post-exposure prophylaxis with HBIG did protect the HBV-exposed chimpanzees, only if HBIG was combined with HB-vaccination or if HBIG was given simultaneously with the HBV inoculum.

PMID: 2809160 [PubMed - indexed for MEDLINE]

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- [Passive immunization of chronic hepatitis B patients on lamivudine therapy: a feasible issue?](#) [J Viral Hepat. 2002]
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